

Protocol Title: Does dexmedetomidine decrease the incidence of untoward airway events after deep or awake extubation in patients undergoing adenotonsillectomy with or without myringotomy and tube placement?

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Statistical Plan

The primary endpoint was the occurrence of one or more postoperative respiratory complications, including desaturation to less than 95% for more than 10 seconds, breath holding, complete or partial laryngospasm, bronchospasm, croup, persistent cough, negative pressure pulmonary edema, and stridor. Secondary outcomes included incidence of emergence agitation, incidence of postoperative nausea and vomiting, length of time from the end of surgery to leaving the operating room, length of stay from admission to PACU to discharge home, 24-hour postoperative pain control, and any unplanned hospital admission due to perioperative respiratory adverse events.

The primary outcome was analyzed by counting the number of patients who experienced any of the listed postoperative respiratory complications. The patients were separated into four groups: awake extubation/dexmedetomidine, awake extubation/placebo, deep extubation/dexmedetomidine, and deep extubation/placebo. The number of patients who experienced any complications was divided by the total number of patients randomized per group. This resulted in the percentage of patients who experienced any postoperative complications.

The secondary outcomes were assessed as following: the number of patients exhibited incidences of agitation, nausea and vomiting were counted; the length of time from end of surgery to leaving the operating room was averaged, the mean and standard deviation per randomization group was reported; the 24-hour postoperative pain control requirement was assessed by counting how many patients needed pain medication post-op for up to 24 hours; and the number of patients who had any unplanned hospital admission due to perioperative respiratory adverse events was counted per randomization group and reported.